

## Issue 21: January 2025

### Cancer-related approvals were 50:50!

This newsletter summarises final decisions from HTA bodies around the world from published reports in January 2025.

**Good news** for: **Enfortumab vedotin**, approved for unresectable or metastatic urothelial carcinoma in France and Germany; **Isavuconazole**, approved for aspergillosis and mucormycosis in Germany; and **Vamorolone**, approved for Duchenne muscular dystrophy in England and Scotland.

**Mixed news** for: **Durvalumab**, approved for resectable NSCLC in England but not approved for advanced or recurrent endometrial cancer in France; and **Elafibranor**, approved with orphan drug status for primary biliary cholangitis in Germany but not approved in France.

**Bad news** for: **Adexanet alfa**, approved for bleeding but application terminated for intracranial haemorrhage in England; **Binimetinib** and **encorafenib**, not approved for advanced NSCLC in Germany; and **Nivolumab**, not approved for NSCLC in Australia.

“  
”  
**37 Approvals**

14 with special arrangements  
5 with orphan drug status

“  
”  
**21 Not approved**  
**4 Excluded submissions**  
**3 Terminated submissions**

“  
”  
**4 Evidence reviews**

# HTANGEL

Issue 21: January 2025

## Pharmacological Technologies



Scotland  
SMC2728

Blood

Paroxysmal nocturnal  
haemoglobinuria  
CROVALIMAB



France  
HAS AP434

Cancer

Advanced non-small  
cell lung cancer  
ADAGRASIB



Scotland  
SMC2675

Blood

Paroxysmal nocturnal  
haemoglobinuria  
DANICOPAN



Germany  
IQWiG A24-73

Cancer

Non-small cell lung  
cancer  
ALECTINIB



Scotland  
SMC2676

Blood

Paroxysmal nocturnal  
haemoglobinuria  
IPTACOPAN



Germany  
IQWiG A24-102

Cancer

Non-small cell lung  
cancer  
ATEZOLIZUMAB



England  
NICE TA1035

Blood

Symptomatic anaemia  
during dialysis for CKD  
VADADUSTAT



Germany  
IQWiG A24-97

Cancer

Non-small cell lung  
cancer  
ATEZOLIZUMAB



# HTANGEL

Issue 21: January 2025

## Pharmacological Technologies



Germany  
IQWiG A24-101

Cancer  
Advanced non-small  
cell lung cancer  
BINIMETINIB,  
ENCORAFENIB

Not  
approved



England  
NICE TA1030

Cancer  
Resectable non-  
small-cell lung cancer  
DURVALUMAB

Approved



Germany  
IQWiG A24-100

Cancer  
Advanced non-small cell  
lung cancer  
BINIMETINIB,  
ENCORAFENIB

Not  
approved



France  
HAS AP427

Cancer  
Advanced or recurrent  
endometrial cancer  
DURVALUMAB, OLAPARIB

Not  
approved



Wales  
AWTTC 5366

Cancer  
Acute lymphoblastic  
leukaemia  
BLINATUMOMAB

Excluded



France  
HAS AP414

Cancer  
Locally advanced or  
metastatic urothelial  
carcinoma  
ENFORTUMAB VEDOTIN

Approved



Germany  
IQWiG A24-105

Cancer  
Locally advanced or  
metastatic breast  
cancer  
CAPIVASERTIB

Not  
approved



Germany  
IQWiG A24-98

Cancer  
Unresectable or  
metastatic urothelial  
carcinoma  
ENFORTUMAB VEDOTIN

Approved



# HTANGEL

Issue 21: January 2025

## Pharmacological Technologies



France  
HAS AP438

**Cancer**  
Locally advanced or  
metastatic  
cholangiocarcinoma  
**IVOSIDENIB**

Approved



Australia  
PBAC

**Cancer**  
Non-small cell lung  
cancer  
**NIVOLUMAB**

Not  
approved



Wales  
AWTTC 4591

**Cancer**  
Relapsed or refractory  
large B-cell lymphomas  
**LISOCABTAGENE  
MARALEUCEL**

Excluded



Wales  
AWTTC 2622

**Cancer**  
Metastatic breast  
cancer  
**OLAPARIB**

Excluded



England  
NICE TA1032

**Cancer**  
Untreated hormone-relapsed  
metastatic prostate cancer  
**NIRAPARIB, ABIRATERONE  
ACETATE, PREDNISONE**

Terminated



Germany  
IQWiG A24-99

**Cancer**  
Unresectable or metastatic  
urothelial carcinoma  
**PEMBROLIZUMAB**

Approved  
with special  
conditions



France  
HAS AP416

**Cancer**  
Desmoid tumours  
**NIROGACESTAT**

Approved



England  
NICE TA1027

**Cancer**  
Uveal melanoma  
**TEBENTAFUSP**

Approved  
with special  
conditions



# HTANGEL

Issue 21: January 2025

## Pharmacological Technologies



France  
HAS AP420

**Cancer**

Gastric and gastroesophageal  
junction adenocarcinoma

**ZOLBETUXIMAB**



Germany  
IQWiG G24-30

**Gastrointestinal  
Primary biliary  
cholangitis**  
**ELAFIBRANOR**



France  
HAS AP419

**Cardiovascular**

Congenital thrombotic  
thrombocytopenic purpura

**APADAMTASE ALFA**



Scotland  
SMC2686

**Gastrointestinal  
Moderately to severely  
active ulcerative colitis**  
**RISANKIZUMAB**



Scotland  
SMC2739

**Eye**

Moderate-to-severe  
Dry Eye Disease

**CICLOSPORIN**



Australia  
PBAC

**Genetic & Metabolic  
Immune-mediated  
inflammatory diseases**  
**ADALIMUMAB**



France  
HAS AP430

**Gastrointestinal  
Primary biliary  
cholangitis**  
**ELAFIBRANOR**



Scotland  
SMC2624

**Genetic & Metabolic  
Molybdenum cofactor  
deficiency (MoCD) Type A**  
**FOSDENOPTERIN**



# HTANGEL

Issue 21: January 2025

## Pharmacological Technologies



Scotland  
SMC2666

**Genitourinary  
Endometriosis**  
RELUGOLIX, ESTRADIOL,  
NORETHISTERONE ACETATE



Germany  
IQWiG G24-26

**Infection  
Acanthamoeba  
keratitis**  
POLIHEXANIDE



Scotland  
SMC2760

**Infection  
HIV-1**  
BICTEGRAVIR,  
EMTRICITABINE, TENOFOVIR  
ALAFENAMIDE



Australia  
PBAC

**Mental Health  
Schizophrenia**  
ARIPIPIRAZOLE



Germany  
IQWiG G24-24

**Infection  
Aspergillosis**  
ISAVUCONAZOLE



Australia  
PBAC

**Mental Health  
Treatment resistant  
depression**  
ESKETAMINE



Germany  
IQWiG G24-25

**Infection  
Mucormycosis**  
ISAVUCONAZOLE



England  
NICE TA1031

**Musculoskeletal  
Duchenne muscular  
dystrophy**  
VAMOROLONE



# HTANGEL

Issue 21: January 2025

## Pharmacological Technologies



Scotland  
SMC2721

Musculoskeletal  
Duchenne muscular  
dystrophy  
VAMOROLONE



Approved



England  
NICE TA697

Other  
Bleeding  
ANDEXANET ALFA



Approved  
with special  
conditions



England  
NICE TA1029

Neurology  
Intracranial  
haemorrhage  
ANDEXANET ALFA

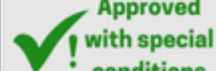


Terminated



England  
NICE TA1034

Other  
Hearing loss  
ANHYDROUS SODIUM  
THIOSULFATE



Approved  
with special  
conditions



Scotland  
SMC2761

Neurology  
Generalised  
myasthenia gravis  
ROZANOLIXIZUMAB



Not  
approved



France  
HAS AP403

Other  
Acute or chronic graft-  
versus-host disease  
RUXOLITINIB

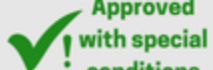


Approved



Scotland  
SMC2731

Neurology  
Relapsing forms of  
multiple sclerosis  
UBLITUXIMAB



Approved  
with special  
conditions



Wales  
AWTTC 6283

Respiratory  
Allergic rhinitis and  
allergic asthma  
12 SQ-HDM



Excluded



# HTANGEL

Issue 21: January 2025

## Pharmacological Technologies



England  
NICE TA1028

Skin

Moderate to severe  
hidradenitis suppurativa  
BIMEKIZUMAB



Germany  
IQWiG A24-107

Skin

Moderate to severe  
chronic hand eczema  
DELGOCITINIB



Scotland  
SMC2710

Skin

Facial angiofibroma  
associated with TSC  
SIROLIMUS



France  
HAS AP426

Skin

Generalized pustular  
psoriasis  
SPESOLIMAB





# HTANGEL

Issue 21: January 2025

## Non-pharmacological Technologies



**Argentina**  
IECS

**Cancer**

Malignant tumours of  
the CNS

STEREOTACTIC  
RADIOSURGERY



**South Korea**  
NECA HTA-2025-1

**Cardiovascular**

Microcystic Lymphatic or  
Microcystic Venolymphatic  
Malformations

RADIOFREQUENCY ABLATION



**South Korea**  
NECA HTA-2025-5

**Cardiovascular**

Uncontrolled  
hypertension

CATHETER-BASED RENAL  
DENERVATION



**England**  
NICE IPG799

**Genitourinary**

Interstitial cystitis or  
overactive bladder

ELECTRICALLY STIMULATED  
INTRAVESICAL THERAPY



**South Korea**  
NECA HTA-2025-6

**Cardiovascular**

Severely calcified  
coronary arteries

CORONARY INTRA  
VASCULAR LITHOTRIPSY



**England**  
NICE IPG798

**Genitourinary**

Lower urinary tract symptoms  
of benign prostatic  
hyperplasia

TRANSPERINEAL LASER  
ABLATION



**Argentina**  
IECS

**Cardiovascular**

Resistant arterial  
hypertension

ENDOVASCULAR RADIOFREQUENCY  
ABLATION WITH A MULTIELECTRODE  
CATHETER



**South Korea**  
NECA HTA-2025-3

**Genitourinary**

Benign prostatic  
hyperplasia

TRANSPERINEAL LASER  
VAPORIZATION



# HTANGEL

Issue 21: January 2025

## Non-pharmacological Technologies



England  
NICE HTE8

Mental Health  
Depression  
DIGITALLY ENABLED  
THERAPIES

Approved  
with special  
conditions



England  
NICE HTE20

Musculoskeletal  
Fractures  
ARTIFICIAL  
INTELLIGENCE

Approved  
with special  
conditions



South Korea  
NECA HTA-2025-2

Musculoskeletal  
Chronic knee pain  
PULSED  
RADIOFREQUENCY

Not  
approved



# HTANGEL

Issue 21: January 2025

## Diagnostic Testing



South Korea  
NECA HTA-2025-4

Other  
Dental caries  
LASER  
FLUORESCENCE



South Korea  
NECA HTA-2024-49

Surgery  
Allogeneic hematopoietic  
stem cell transplantation  
CHIMERISM TESTING



# HTANGEL

Issue 21: January 2025

## Other Guidance



Spain  
AETSA

**Cancer**  
**Cancers**  
NONINVASIVE  
LOCOREGIONAL  
HYPERThERMIA

 Evidence  
review



Ireland  
HIQA

**Infection**  
**Respiratory syncytial  
virus**  
RSV VACCINE

 Evidence  
review



Canada  
CDA RC1569

**Mental Health**  
Assorted mental health  
conditions  
VIRTUAL MENTAL  
HEALTH COUNSELLING

 Evidence  
review



Canada  
CDA RC1565

**Surgery**  
**Pain management**  
METHADONE

 Evidence  
review

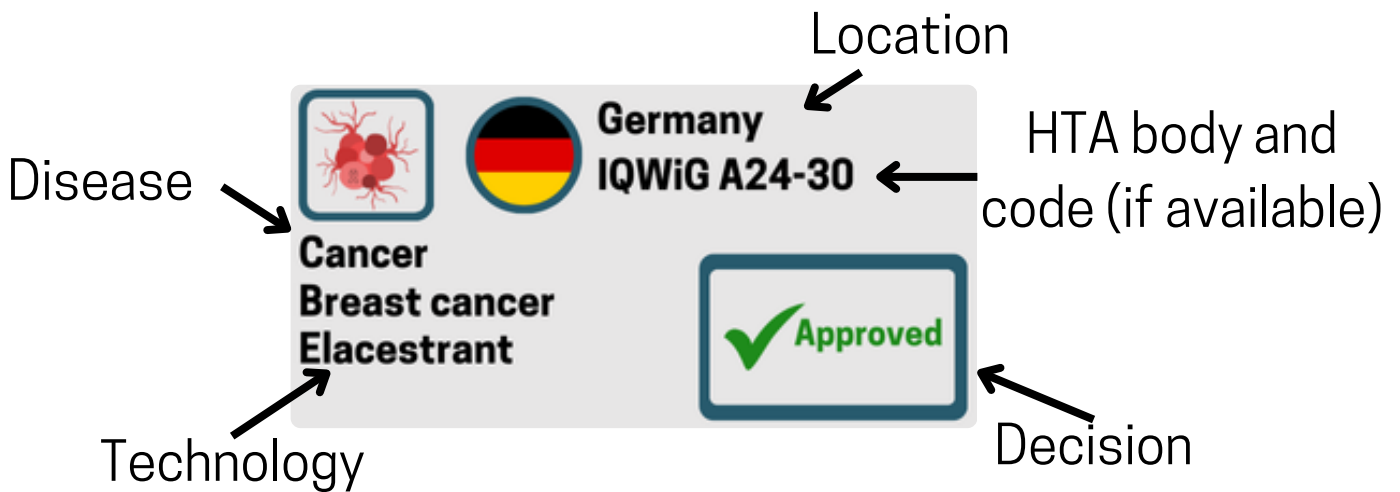


# HTANGEL

Issue 21: January 2025

## Further Information

HTAngel is designed to help keep you up to date with the latest HTA decisions around the world. Below is a breakdown of the tiles in the newsletter.



At Crystallise we aim to provide an innovative approach to processing information, using software tools to automate processes that are slower and less accurate when done by humans. Our approach provides clients with greater transparency and scope than they could find for the same budget elsewhere. We work with a network of experts and organisations that help us support clients efficiently and effectively, and are proud of our flexible and ingenious way of solving their problems.

For further information about HTAngel contact [newsletter@crystallise.com](mailto:newsletter@crystallise.com)

To speak to us about our services contact [contact@crystallise.com](mailto:contact@crystallise.com)

